



Application Serial No. 09/677,737
Attorney Docket No. JBP-525

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REMARKS

I. Status of the Claims

Claims 1, 2, 7, 12 and 16 have been amended to more clearly define that which Applicants regard as their invention. Support for the amendment to claim 1 can be found in the Specification, at least at page 2, lines 6-10. Support for the amendment to claims 2 and 16 can be found in the Specification, at least at page 3, line 21. Claims 7 and 12 have been amended to delete the phrase "derivatives thereof." Accordingly, no new matter has been introduced by this Amendment.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is/are captioned "Version With Markings To Show Changes Made."

II. Claim Rejections - 35 U.S.C. § 112

A. The Examiner has rejected claims 3 and 13 as vague and indefinite because the term "dimethylaminoethanol" lacks antecedent basis. Applicants have amended claims 2 and 12 to provide adequate antecedent basis for dimethylaminoethanol. Accordingly, Applicants respectfully request that the rejection be withdrawn.

B. The Examiner has rejected claims 7 and 16 as allegedly vague and indefinite because of the phrases "derivatives thereof" and "natural plant extracts." Applicants respectfully traverse this rejection. First, one of ordinary skill in the art would understand the alpha-hydroxy acid derivatives contemplated by the present invention. Nevertheless, solely in an effort to expedite prosecution, Applicants have removed this phrase from claims 7 and 16.

With respect to the phrase "natural plant extracts," Applicants respectfully submit that this phrase is meant to cover plant extracts that occur naturally, in other words, plant

extracts that are not synthetically derived. One of ordinary skill in the art would clearly understand the types of plant extracts covered by this phrase. Accordingly, Applicants respectfully request withdrawal of this rejection.

III. Claim Rejections 35 U.S.C. § 102

The Examiner has rejected claims 1-16 as allegedly anticipated by U.S. Patent No. 6,162,419 ("the '419 patent"). Applicants respectfully traverse this rejection.

The '419 patent relates to methods for stabilizing and solubilizing an ascorbic acid compound in a composition with at least one water-soluble ingredient. The method comprises dissolving, homogeneously mixing, or stably dispersing the ascorbyl acid compound in a solvent and adding the dissolved, homogeneously mixed, or stably dispersed solvent phase containing the ascorbic acid compound to an aqueous phase containing the water-soluble ingredient. According to the '419 patent, ascorbic acid compounds are useful for treating a wide variety of skin diseases and skin conditions. See col. 1, line 9 – col. 3, line 4. Clearly, the ascorbic acid compound is the active ingredient in the compositions taught by the '419 patent.

In contrast to the methods and compositions of the '419 patent, the present invention relates to a method for ameliorating redness or inflammation of mammalian skin by topically applying a composition comprising:

- (a) an effective amount of a redness or inflammation reducing agent selected from the group consisting of an alkanolamine; tyrosine; or a mixture thereof; and
- (b) a cosmetically acceptable carrier.

There is no teaching or suggestion in the '419 patent that an alkanolamine or tyrosine could be used as a redness or inflammation reducing agent. The Examiner argues that the claimed function of ameliorating redness or inflammation of the skin is inherent in the compositions of '419. Applicants respectfully disagree. The fact that a certain result or

characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result of characteristic. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. See M.P.E.P. § 2112. Here, there is nothing in the teachings of the '419 patent that would reasonably support the determination that an alkanolamine or tyrosine could be used as a redness or inflammation reducing agent as claimed in Applicants claimed invention. Accordingly, Applicants respectfully submit that the '419 patent fails to anticipate the claimed invention.

Same
herein

IV. Claim Rejections 35 U.S.C. § 102/103

The Examiner has rejected claims 1-16 as allegedly anticipated by, or in the alternative unpatentable over U.S. Patent No. 5,643,586 (the '586 patent').

The '586 patent relates to a method for the topical treatment of subcutaneous muscle and overlying cutaneous tissue comprising topically applying to affected skin areas a composition comprising (a) a catecholamine precursor; (b) an effective amount of ascorbyl palmitate; and (c) a dimethylaminoethanol, in a dermatologically acceptable carrier that penetrates the skin so that muscle tone in subcutaneous muscle tissue is increased.

In contrast to the methods and compositions of the '419 patent, the present invention relates to a method for ameliorating redness or inflammation of mammalian skin by topically applying a composition comprising:

- (a) an effective amount of a redness or inflammation reducing agent selected from the group consisting of an alkanolamine; tyrosine; or a mixture thereof; and
- (c) a cosmetically acceptable carrier.

The Examiner argues that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to have adapted the composition in Perricone to use it for inflammatory skin disease, as suggested by the reference." First, Applicants respectfully

submit that there is no teaching or suggestion in the '419 patent that an alkanolamine or tyrosine could be used as a redness or inflammation reducing agent. The Examiner is respectfully request to point out where in the teachings of the '419 patent is it suggested to use that an alkanolamine or tyrosine as a redness or inflammation reducing agent. Further, as the Examiner is well aware, a new use of known process, composition of matter, or material is patentable. See, for example, M.P.E.P. § 2112.02 and *In re Zierden*, 411 F.2d 1325, 1329 (C.C.P.A. 1969). Accordingly, Applicants respectfully submit that the claimed invention is neither anticipated by nor obvious in view of the '419 patent.

V. Conclusion

Applicants believe that the foregoing presents a full and complete response to the outstanding Office Action. An early and favorable response to this Amendment is earnestly solicited. If the Examiner feels that a discussion with Applicants' representative would be helpful in resolving the outstanding issues, the Examiner is invited to contact Applicants' representative at the number provided below.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/JBP-525/EMH. If a fee is required for an Extension of time 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

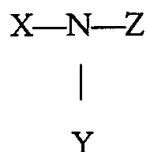
IN THE CLAIMS:

1. A method for ameliorating redness or inflammation of mammalian skin by topically applying a composition comprising:

(d) an effective amount of a redness or inflammation reducing agent ~~at least one compound~~ selected from the group consisting of an alkanolamine; tyrosine; or a mixture thereof; and

(b) a cosmetically acceptable carrier;

wherein said alkanolamine has the following general formula:



wherein X, Y and Z are selected from the group consisting of hydrogen, C₁-C₃ alkyl group, C₂-C₄ alkanol group, wherein at least one of X, Y or Z is a C₂-C₄ alkanol group bearing at least one hydroxyl group and optionally at least one carboxyl group.

2. A method according to claim 1, wherein said alkanolamine is selected from the group consisting of ethylaminoethanol, methylaminoethanol, dimethylaminoethanol-~~amine~~, isopropanolamine, triethanolamine, isopropanoldimethylamine, ethylethanol-amine, 2-butanolamine, choline and serine.

7. A method according to claim 1, wherein the irritating ingredient is selected from a retinoid, benzoyl peroxide, alpha - hydroxyacids ~~and derivatives thereof~~, salicylic acid, surfactants, soaps, natural plant extracts, sunscreen actives, urea, preservatives.

12. A method according to claim 11, wherein said alkanolamine is selected from the group consisting of ethylaminoethanol, methylaminoethanol, dimethylaminoethanol-~~amine~~, isopropanolamine, triethanolamine, isopropanoldimethylamine, ethylethanol-amine, 2-butanolamine, choline and serine.
16. A method according to claim 11, wherein the skin irritating composition comprises an irritant selected from a retinoid, benzoyl peroxide, alpha-hydroxyacids ~~and derivatives thereof~~, salicylic acid, surfactants, soaps, natural plant extracts, sunscreen actives, urea, and preservatives.